

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

A. Burchell et al.

Examiner:

Lisa V. Cook

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PRENATAL DIAGNOSTIC METHODS

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Elizabeth Bui

AMENDMENT AND RESPONSE TO OFFICE ACTION

Mail Stop Fee Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir/Madam:

This paper is in response to the Office Action dated September 24, 2003. By the Petition for a One Month Extension enclosed herewith, the date for responding is extended to January 24, 2003.

Please amend the claims as follows.

- 1. (Previously canceled)
- 2. (Currently amended) A method of isolating embryonic or fetal red blood cells from a sample containing maternal blood cells and embryonic or fetal red blood cells or both, the method comprising determining which cell or cells contain or express an adult liver

component that is a cell surface exposed component, wherein the adult liver component is not transferrin receptor, the method comprising the steps of:

- (a) contacting the sample with a [reagent] <u>binding moiety</u> that specifically binds the adult liver component;
- (b) allowing the [reagent] <u>binding moiety</u> to bind to the adult liver component; and
- (c) isolating the embryonic or fetal red blood cells by virtue of being bound to the [reagent] binding moiety.
- 3. (Currently amended) A method according to Claim [1 or] 2 wherein the sample is a sample of blood from a pregnant female.
- 4. (original) A method according to Claim 3 wherein the pregnant female is a human female and the sample is taken in the first trimester.
- 5. (Currently amended) A method according to Claim [1 or] 2 wherein the embryonic or fetal red blood cell is of the nucleated megaloblastic series.
- 6. (Currently amended) A method according to Claim [1 or] 2 wherein the adult liver component is a protein.
- 7. (currently amended) A method according to Claim [1 or] 2 wherein the adult liver component is present, when compared to embryonic or fetal red blood cells, at less than 1 percent on a per-cell basis in maternal cells of the maternal blood.
 - 8. (Previously canceled)
- 9. (Currently amended) A method of isolating embryonic or fetal red blood cells in a sample containing maternal blood cells and embryonic or fetal red blood cells or both,

the method comprising isolating the cells which contain or express a component selected from the group consisting of glucose transporter 2 (GLUT2), a P-glycoprotein, a multi-drug resistance protein (MDRP), a multi-drug resistance-like protein (MRP), γ-glutamyl transpeptidase, a lipoprotein receptor, an alkaline phosphatase, a bile salt transporter, a hormone receptor, a multiple organic ion transporter (MOAT), a bilirubin transporter, and a bilirubin conjugate transporter, the method comprising the steps of:

- (a) contacting the sample with a [reagent] <u>binding moiety</u> that specifically binds the component;
 - (b) allowing the [reagent] binding moiety to bind to the component; and
- (c) isolating the embryonic or fetal red blood cells by virtue of being bound to the [reagent] binding moiety.
 - 10. (Canceled)
 - 11. (Canceled)
- 12. (Currently amended) A method according to Claim [10] <u>2 or 9</u> wherein the binding moiety is an antibody or fragment or derivative thereof.
- 13. (original) A method of isolating embryonic or fetal red blood cells from a sample according to Claim 12 wherein the binding moiety is immobilized to a solid support.
- 14. (original) A method according to Claim 10 wherein the binding moiety is detectably labeled or is capable of detection.
- 15. (original) A method of isolating embryonic or fetal red blood cells from a sample according to Claim 14 wherein the label facilitates isolation of the cells.
 - 16. (Canceled)
 - 17. (Previously canceled)

- 18. (Previously canceled)
- 19. (Previously canceled)
- 20. (Previously canceled)
- 21. (Previously canceled)
- 22. (Previously canceled)
 - 23. (Previously canceled)